ORIGINAL

FILED IN COURT CHARLOTTE, N. C.

JUN 8 2006

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION

U. S. DISTRICT COURT W. DIST. OF N. C.

UNITED STATES OF AMERICA)	DOCKET NO. 3:04CR201-Mu
)	PLEA AGREEMENT
V.)	FLEA AGREEMENT
VINTAGE PHARMACEUTICALS, INC.	Ś	

NOW COMES the United States of America, by and through Gretchen C.F. Shappert, United States Attorney for the Western District of North Carolina, and the defendant, Vintage Pharmaceuticals, Inc. ("Vintage"), through its Chief Executive Officer, Thomas J. Young, and through counsel for Vintage, Mark Brown, and respectfully inform the Court that they have reached the following agreement:

I. Plea

- 1. The defendant agrees to enter a voluntary plea of guilty to the offense of delivery for introduction into commerce an adulterated drug within the meaning of 21 U.S.C. § 351(a)(2)(B), in violation of 21 U.S.C. § 331(a) and 21 U.S.C. 333(a)(2), as set forth in Counts Twenty-One through Thirty-Nine of the Superseding Bill of Indictment, and, on the basis of the factual recitation set forth in the Factual Resume attached hereto, admits to being in fact guilty of the offenses charged in Counts Twenty-One through Thirty-Nine.
- 2. If the Court finds the defendant's plea to be voluntary and knowingly made, and accepts the plea, then the United States will move immediately following the announcement of the sentence to dismiss Counts One through Twenty and Forty through Sixty-One as set forth in the Superseding Bill of Indictment and will dismiss the notice of forfeiture provisions without prejudice to the forfeiture provisions in this agreement.
- 3. The defendant agrees that the Court may consider any such dismissed count and all pertinent information as "relevant conduct," *United States Sentencing Guidelines [U.S.S.G.] §* 181.3. The Court may also consider any dismissed count as a "conviction" for purposes of 28 U.S.C. §§ 1918 (costs of prosecutions, including fines and forfeitures), 920 (court costs, including fees for interpreters), as well as for purposes of forfeiture and restitution.

II. Sentence

4. The defendant is aware that the statutory maximum sentence for each count, pursuant to 21 U.S.C. § 333(a)(2) and 18 U.S.C. § 3571, the statutory maximum sentences for each count is as follows:

- 5. The defendant is aware that the Court will consider the *United States Sentencing Guidelines [U.S.S.G.]* in determining the appropriate sentence. The defendant is further aware that the Court has not yet determined the sentence, but that, pursuant to Fed. R. Crim. P. 11(c)(1)(C), the agreements between the parties set forth below are binding on the Court once the Court accepts the plea agreement.
- 6. Purusant to Fed. R. Crim P. 11(c)(1)(C), the parties stipulate and agree that the following sentence is appropriate for the disposition of this case:
 - a. The adjusted offense level for the subject offenses is 22, and the specific characteristics are set forth in Attachment A.
 - b. a fine, based on the range set forth in U.S.S.G. § 8C2.1 et seq. and the departures set forth in U.S.S.G. § 8C3.4 is \$4,800,000.00.
 - c. Defendant shall forfeit as criminal proceeds \$1,200,000.00, said amount which relates to the adulterated lots set forth in Counts Twenty-One through Thirty-Nine.
- 7. If the fine and/or any assessment owed to the United States is not paid within ten days of sentencing, a lien will be filed. The defendant understands that if a lien is filed against its property, its obligation to pay restitution shall last for twenty years. 18 U.S.C. § 3613.
- 7600.00) The defendant hereby agrees to pay the total amount required for assessment (\$1900.00) to the Clerk, United States District Court, before 5:00 p.m. on the date of pleading guilty.
- 9. The Food and Drug Administration ("FDA") represents and agrees that the conduct for which the defendant pleads guilty does not relate to the development or approval, including the process for development or approval, of any abbreviated drug application.
- 10. The sentence set forth in this plea agreement is covered by Fed. R. Crim. P. 11(c)(1)(C). If the Court does not accept any aspect of the proposed sentence or any other binding aspect of this plea agreement, then (a) the defendant is free to withdraw its plea of guilty; (b) this plea agreement (and the waivers herein) shall be null and void; (c) the defendant shall have the right to reinstate any motions that have been withdrawn; and (d) any statements or admissions by the defendant contained in the attached factual basis or elsewhere in this plea agreement shall be treated as statements of the defendant made pursuant to Rule 410 of the Federal Rules of Evidence and/or Fed. R. Crim. P. 11(f).

III. Procedure

11. The defendant stipulates that there is a factual basis for the plea of guilty, as required by Fed. R. Crim. P. 11(b)(3), and that the factual basis is attached as the Factual Resume attached hereto and is incorporated herein to this plea agreement.

IV. Waivers

- 12. The defendant understands and agrees that if he should fail to specifically perform or to fulfill completely each and every one of its obligations under this Plea Agreement, then the United States will be relieved of its obligations under the agreement, but the defendant will not be allowed to withdraw its guilty plea.
- 13. The defendant is aware that the law provides certain limited rights to withdraw a plea of guilty. The defendant has discussed these rights with defense counsel and knowingly and expressly waives any right to withdraw the plea once the District Court has accepted it.
- 14. The defendant acknowledges that Federal Rule of Criminal Procedure 11(f) and Federal Rule of Evidence 410 are rules which ordinarily limit the admissibility of statements made by a defendant in the course of plea discussions or plea proceedings if a guilty plea is later withdrawn after it is accepted by the Court. The defendant knowingly and voluntarily waives these rights to the extent that any statements which are made in the course of its guilty plea or in connection with its cooperation pursuant to this plea agreement will be admissible against it for any purpose in any criminal or civil proceeding if its guilty plea is subsequently withdrawn after it is accepted by the Court.
- 15. The defendant understands and agrees that by pleading guilty, he is expressly waiving the following rights:
 - a. to be tried by a jury;
 - b. to be assisted by an attorney at trial;
 - c. to confront and cross-examine witnesses; and,
 - d. not to be compelled to incriminate itself.
- 16. Defendant and defendant's counsel warrant that they have discussed: (1) defendant's rights pursuant to 18 U.S.C. § 3742 and similar authorities to contest a conviction and/or sentence through an appeal or post-conviction after entering into a plea agreement; (2) whether or not there are potential issues which might be relevant to an appeal or post-conviction action; and (3) the possible impact of any such issue on the desirability to the defendant of entering into this plea agreement.

Defendant, in exchange for the concessions made by the United States in this plea agreement, waives all such rights to contest the conviction and/or the sentence except for: (1) claims of

ineffective assistance of counsel; (2) prosecutorial misconduct; or (3) the sentence, but only to the extent defendant contests the sentence on the basis that one or more findings on guideline issues were inconsistent with the explicit stipulations contained in any paragraph in the plea agreement filed herein, or on the basis of an unanticipated issue that arises during the sentencing hearing and which the District Judge finds and certifies to be of such an unusual nature as to require review by the Fourth Circuit Court of Appeals.

Also, in exchange for the concessions made by the United States, defendant agrees that the United States preserves all its rights and duties with respect to appeal as set forth in 18 U.S.C. § 3742(b), while the defendant waives all rights to appeal or collaterally attack the sentence of conviction with the three exceptions set forth above. This agreement does not limit the United States in its comments in or responses to any post-conviction matters.

- 17. The defendant waives all rights, whether asserted directly or by a representative, to request or to receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.
- 18. In exchange for the guilty plea of defendant and the performance of his obligations under this plea agreement, the United States Attorney for the Western District of North Carolina agrees not to file any criminal or civil action (other than those necessary to effectuate the defendant's obligations under this agreement) against the defendant, William Propst, Sr., William Propst, Jr., or Qualitest Pharmaceuticals, Inc. arising from the government's investigation of Vintage Pharmaceuticals, Inc. or Qualitest Pharmaceuticals, Inc. during the period specified in the Superseding Indictment. Further, FDA will not pursue any further criminal, civil or administrative action for the conduct which is alleged in the Superseding Indictment in this case and which is known to FDA as of the date of this plea agreement. This agreement is binding only on the Western District of North Carolina and the FDA and does not preclude any prosecution involving crimes of violence, violations of Title 26 of the United States Code, and/or information unknown to the government at the time this plea agreement is executed.

V. Forfeiture

- 19. The defendant forfeits and otherwise waives any ownership right in \$1,200,000.00 in criminal proceeds.
- 20. This agreement does not bind the Internal Revenue Service or affect its authority to collect taxes.
 - 21. By this agreement, the defendant agrees to forfeit all interest in the \$1,200,000.00 and

to take whatever steps necessary to effectuate the payment of the forfeited funds, including, but not limited to the signing of a consent judgment and signing any other documents necessary to effectuate such transfer.

- 22. Defendant agrees to the entry of a consent order and judgment of forfeiture as to all of defendant's interest in this property. Defendant has surrendered or will surrender the property to the United States Marshal or other agent of the United States. To the extent that any of this property was not included in a notice of forfeiture in the Bill of Indictment, defendant waives all rights under Fed. R. Crim. P. 32.2(a).
- 23. The defendant agrees to waive any rights under the Speedy Trial Act and understands and agrees that sentencing may be delayed until the cooperation phase has been completed and title to all assets have fully vested in the United States. This waiver is necessary so that the Court will have the benefit of all relevant information at sentencing.

VI. Conclusion

- 24. The defendant understands that if he breaches this Plea Agreement, or violates any federal, state or local law, or any order of any court, including any condition of pre-trial or presentence, or post-sentence release, the United States will be relieved of its obligations under this Plea Agreement, but the defendant will not be allowed to withdraw its guilty plea. The United States will be free to proceed on any properly-filed dismissed, pending, superseding, or additional charges.
- 25. The United States agrees, immediately after the announcement of the sentence of the defendant, to dismiss all charges against Qualitest Pharmaceutical, Inc. with prejudice.
- 26. There are no agreements, representations, or understandings between the parties in this case, other than those explicitly set forth in this Plea Agreement and none will be entered into unless executed in writing and signed by all parties.

SO AGREED!	DATED: 8/6/05
Gretchen C.F. Shappert, United States Attorney	
Michael E. Savage, Assistant United States Attorney	
Jennifer Caruso, Special Assistant United States Attorney and Associate to the Chief Counsel, FDA (on behalf of the FDA)	DATED: 8/6/06
Mark Brown, Attorney for Defendant	DATED: 6/8/96
Vintage Pharmaconticals And Defendant	DATED: <u>6/8/</u> 06

By Thomas J. Young, Chief Executive Officer of Vintage Pharmaceuticals, Inc.

ATTACHMENT A

Base Offense Level [U.S.S.G. §§ 2F1.1, 8C1.1]: 6

The amount of loss that was known to or reasonably foreseeable by the defendant was in excess of \$600,000.00.

The defendant understands that "loss" under U.S.S.G. § 2F1.1 of the *United States Sentencing Guidelines* may be different from, greater, or lesser than "restitution" under 18 U.S.C. § 3556.

Specific Characteristics:

Adjusted Offense Level:		22
•	U.S.S.G. § 2F1.1(b)(6)	+2
•	U.S.S.G. § 2F1.1(b)(4)	+2
•	U.S.S.G. § 2F1.1(b)(2)	+2
•	U.S.S.G. § 2F1.1(b)(1)(K)	+10